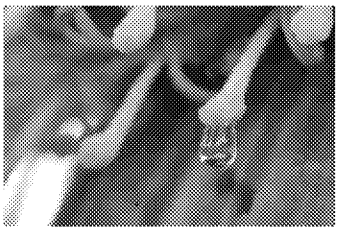
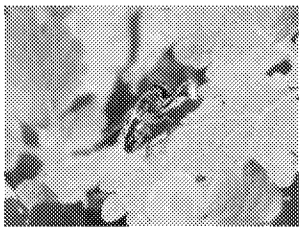




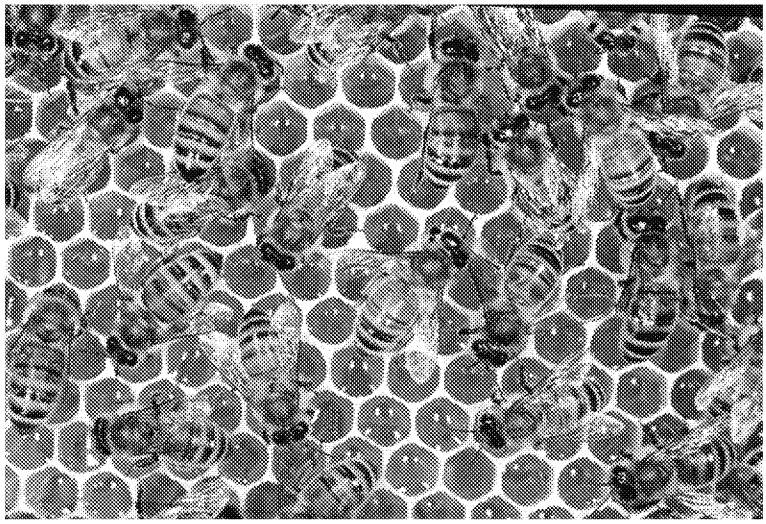
Overview of Assessing Pesticide Risks to Pollinators

2019 EFED Training Program

EPA

Outline

1. **U.S. Bee Declines**
   - Historical perspective
   - Associated factors
2. **Regulatory Framework**
   - Development
   - Overview
   - Tier by Tier Walkthrough
3. **Novel Approaches**
   - Residue Bridging Strategy
   - Pollen Method
4. **Case Study**
5. **Future Work**

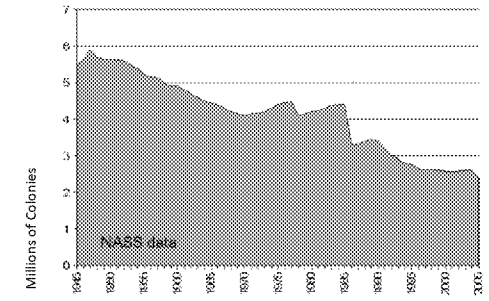


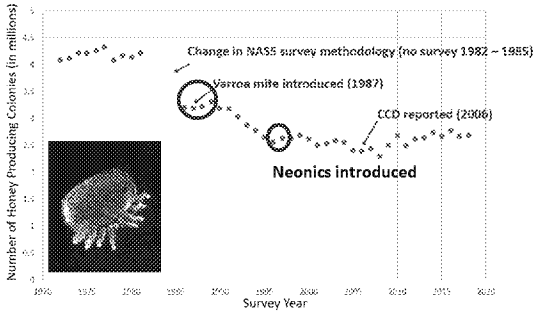
EPA

Honey Bee Declines

National Agricultural Statistics Survey (NASS)

- Declines in managed honey bee colonies; peak of approximately 6 million colonies in 1947 to roughly 2.8 million in 2006 (USDA 2008)
- Change in survey methodology in mid-1980s
- Varroa mite introduction (1987) followed by decline in managed colony numbers
- Numbers have leveled off since 1996
- As of 2018; 2.69 million colonies





EPA

Factors Associated with Colony Losses

PATHOGENS/PARASITES

Nosema

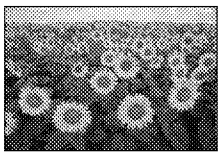
Bacteria

Viruses

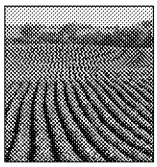
Fungi

Parasites

Other Insects

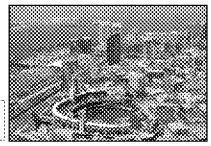


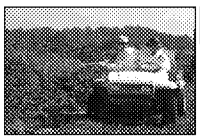
NUTRITION



AGRICULTURAL PRACTICES

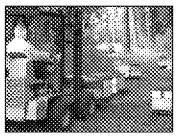
URBANIZATION





PESTICIDES

BEE MANAGEMENT PRACTICES

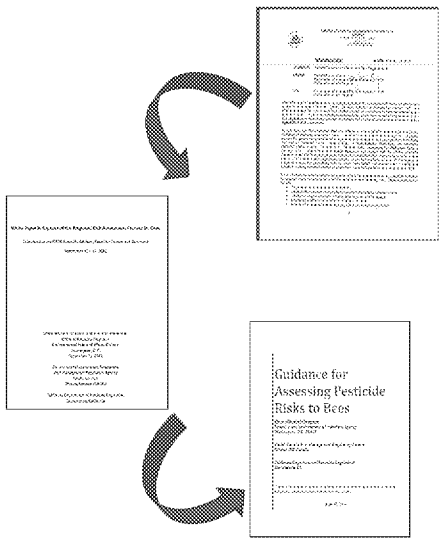


EPA

Source: USDA Agricultural Research Service

Regulatory Framework Development

- **2011: Interim Guidance on Honey Bee Data Requirements**
- **2012: Pollinator Risk Assessment Framework White Paper**
  - Developed with PMRA and CDPR
  - Supported SAP
- **2014: Final EPA Guidance on Risk Assessments for Pollinating Bees**
  - Harmonized guidance; served as template for Mexico and Australia



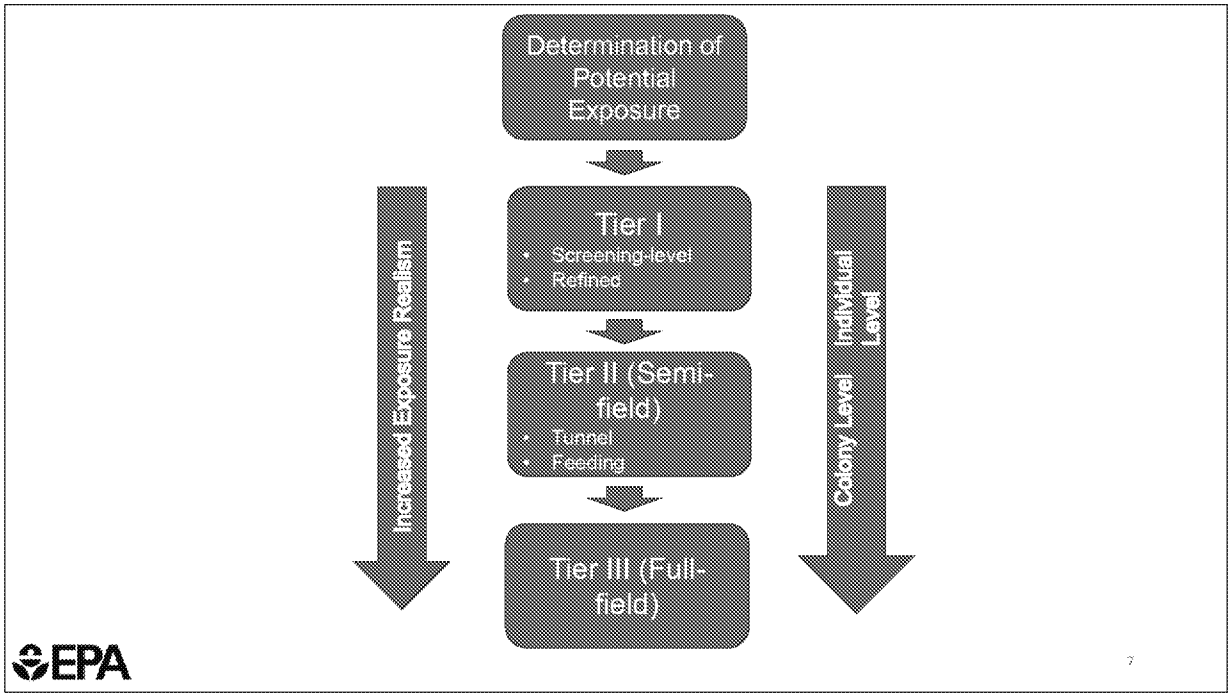
EPA

Framework Scope

Management Goal	Assessment Endpoint	Example Measurement Endpoints
Provision of pollination services	Population size/ stability	Population: colony strength & survival Individual: org. survival, growth, repro.
Production of hive products	Quantity/quality of hive products	Population: hive product production, quality (honey, wax, propolis) Individual: org. survival, growth, repro.
Contribution to bee biodiversity	Species richness/ abundance	Community/Population: species richness, abundance, colony strength Individual: org. survival, growth, repro.

- **Assessment process is *Apis* centric:**
  - Importance in pollination services & hive products
  - Availability of data (exposure & effects)
  - Quality of data (standardized test guidelines)
  - Quantifiable exposure estimates

EPA


Determination of Potential Exposure
Tier I
Screening-level
Refined
Tier II (Semi-field)
Tunnel
Feeding
Tier III (Full-field)
Increased Exposure Realism
Colony Level
Individual Level
EPA

Determination of Potential Exposure

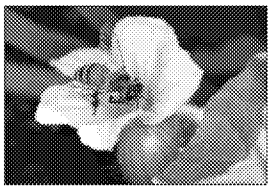
- Crop attractiveness
- Agronomic practices

EPA

USDA

United States Department of Agriculture

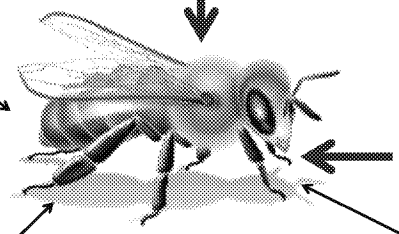
Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen



Exposure Routes

Contact: Direct spray (adult foragers)

Inhalation: Spray droplets or gaseous phase of chemical



Oral: Collection, processing and consumption of contaminated pollen, nectar

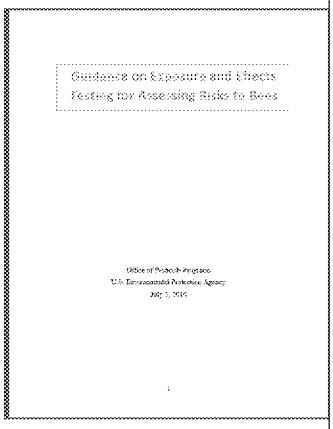
Contact: With contaminated foliage, soil, comb wax, propolis and/or pollen, fugitive dust

Oral: Consumption of contaminated drinking water and guttation fluid

EPA

Tier I Dataset

- **Adult acute contact/oral (OCSPP 850.3020/OECD TG 213)**
  - Single oral or contact exposure
  - 96-hour observation period
  - LD_{50} and sublethal effects reported
- **Adult chronic oral 10-day (OECD TG 245)**
  - Continuous oral exposure
  - Mortality and food consumption NOAEC/LOAEC reported
- **Larval acute (OECD TG 237)**
  - Single exposure, 72 hour observation
  - LD_{50} reported
- **Larval chronic 22-day (OECD Guidance Document 239)**
  - Repeat exposure from D3 – D6
  - NOAEC/LOAEC for mortality/emergence reported at D22



EPA

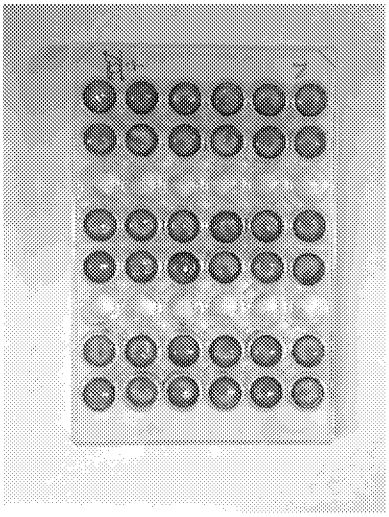
Default Tier I Assessment

- The goal is to generate "reasonably conservative" estimates of exposure

- Intended to distinguish between:
  - Pesticides that do not pose a risk to bees; and
  - Pesticides that may need additional information

- Uses deterministic approach
  - Involves Risk Quotients (RQs) derived from
    - Estimated exposure concentration (EEC)
    - Honey bee toxicity data (individual based, laboratory studies)
  - If RQ exceeds Level of Concern (LOC), there is risk of effects and refinement may be needed

- Implemented using BeeREX model



EPA

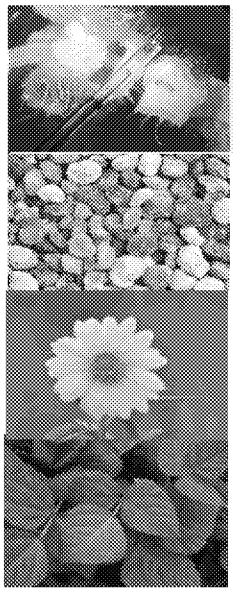
11

Refined Tier I Assessment
Default Tier I Assessment

- Foliar/Soil/Seed treatment exposure inputs in Bee-REX
  - Foliar – Single maximum rate
  - Soil – Single maximum rate, Koc, Log K_{OW}
  - Seed – 1 mg/kg default

If RQ > LOC

- Derive RQs with empirical data for chemical-specific concentrations in pollen and nectar
  - Acute: maximum concentration from single samples
  - Chronic: maximum daily mean of all days collected
- Tier I Default consumption rates and toxicity endpoints remain

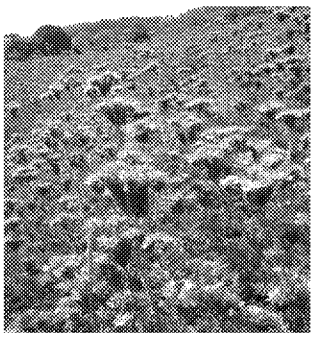


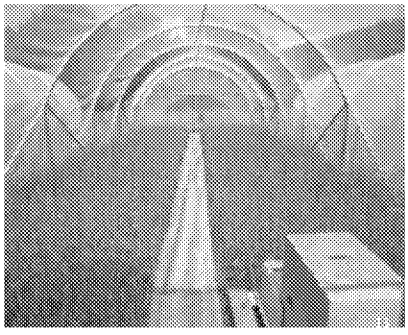
EPA

Tier 2 (Semi-field) Effects Studies - Tunnel

- Maximize exposure by confining a small hive of bees to a particular crop or bee attractive plant
  - Typically with *Phacelia*
- Pesticide applied according to label specifications or worst-case (during bloom while bees are foraging)
- Exposure period can vary, but typically 7-10 days
- OECD TG 75, EPPO 170 Guidance

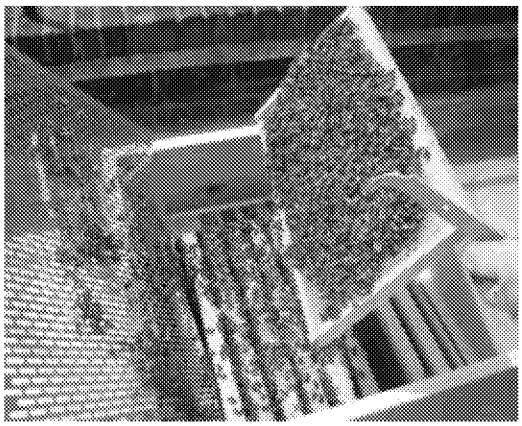
EPA





Tier 2 (Semi-field) Effects Studies – Colony Feeding Study (CFS)

- Various concentrations of pesticide fed to bees in the hive
- Bees allowed to forage freely
- Replication of hives in each treatment group
- Multiple endpoints examined
- Allows for long term monitoring of effects
- 2 primary designs:
  - Oomen et al (1992)
  - Extended feeding (current design)

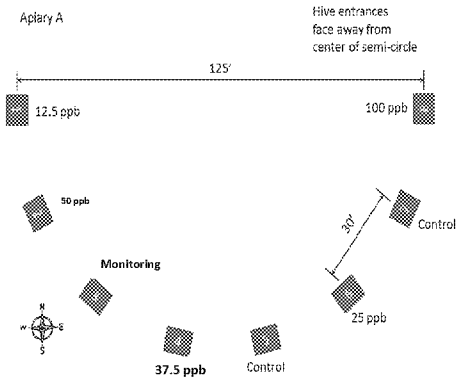


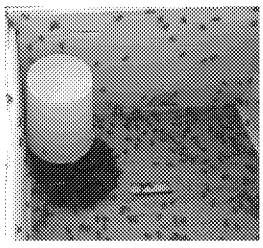
EPA

14

(Extended) Colony Feeding Study

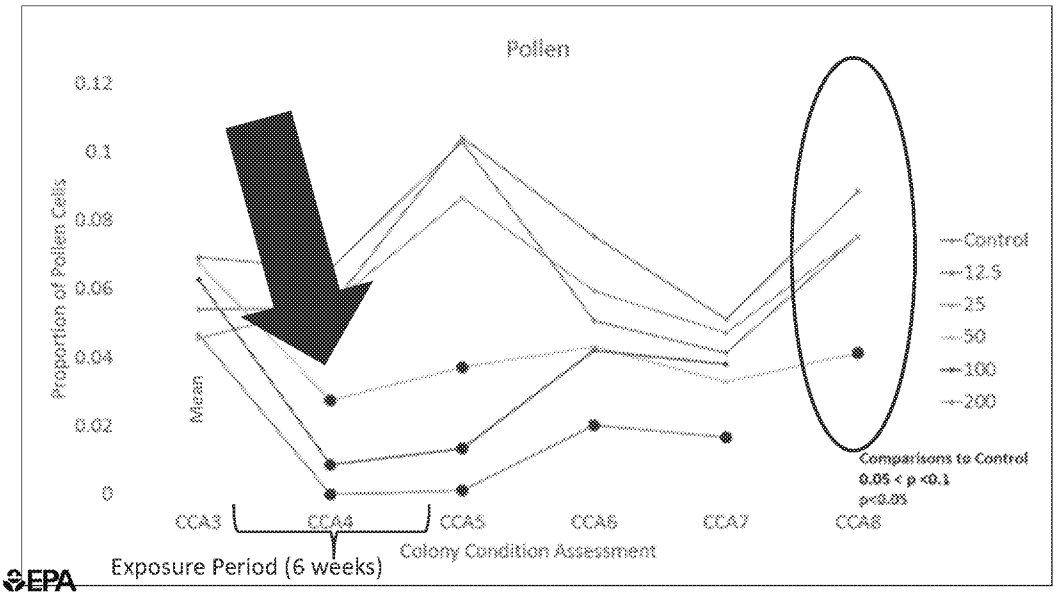
- High number of replicates (apiaries) per treatment
  - Typically with an unbalanced design
- Colonies typically fed for 6 weeks via sucrose solution in hive
- Continued monitoring of colonies before, during, and after exposure including overwintering
- Colony Condition Assessments (CCA)
  - Percent coverage of frames by adults, eggs, larvae, pupae as well as pollen and nectar/honey stores
  - Analysis of effects at each CCA and inspection of trends across the CCAs





EPA

CFS Results Example



EPA

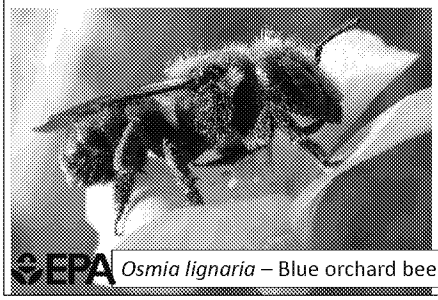
Tier III – Full Field Studies

- Most environmentally realistic scenario
  - Hives placed in field where labeled application to crop occurs
- Similar endpoints, duration of monitoring as Tier II CFS
- Experimental unit is the field
- Pollen analysis to quantify level of exposure
- Not frequently available

EPA

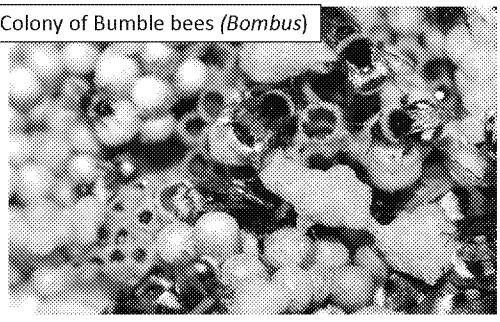
Non-*Apis* Bee Risk Characterization

- ~ 4,000 species of non-*Apis* bees in U.S.
- Differences in biology, ecology expected to lead to different exposures vs. *Apis*
- Relevant to pollinator protection goals (commercial pollination services, biodiversity)
- Tier I risk assessment methods and data currently lacking
  - Limited data suggest honey bee is protective of bumble bees and solitary species



Osmia lignaria – Blue orchard bee

Colony of Bumble bees *(Bombus)*



Megachile rotundata – Alfalfa leafcutter bee

Novel Approaches - Residue Bridging Strategy

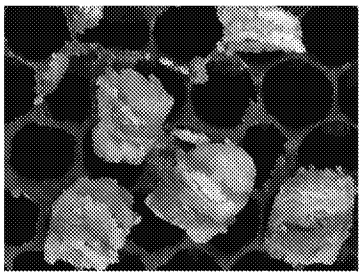
- Using ~80 neonic residue studies, EFED developed methods to reduce uncertainties associated with:
  - **Lack of data** (missing chemical/crop/method)
  - **Data limitations** (sparse temporal, spatial coverage, missing matrix)

- Determined the major, quantifiable variables that influence residue levels
  - Application method, application timing, and site
  - Crop does sometimes influence concentrations

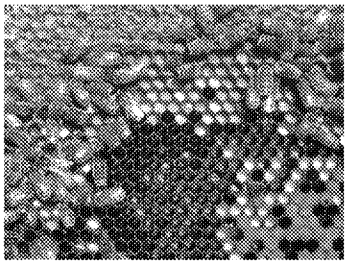
- Developed approach for incorporating residue data into risk assessment
  - Derive Tier 1 (refined) and Tier 2 exposure concentrations
  - For uses with data to quantify kinetics of residue declines, Monte Carlo analyses were utilized
    - Allowed for calculation of the number of days required for residues to drop below the toxicity endpoint.

EPA

Novel Approaches – Tier II Pollen Method



- Honey bee colonies consume more nectar than pollen
  - If concentrations in pollen and nectar are equal, dose from nectar will be greater
- Available information suggest that on a concentration basis, colony level endpoints for nectar should be lower than pollen

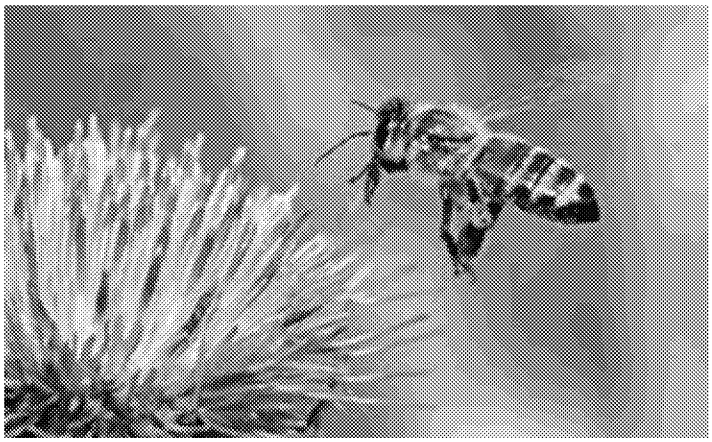


- Available lines of evidence indicate that difference in contribution of colony's dose from pollen is 20x less than that of nectar
- Final equation:

$$C_{total} = C_{nectar} + \frac{C_{pollen}}{20}$$

EPA

Case Study - Imidacloprid



EPA

Uses of Imidacloprid

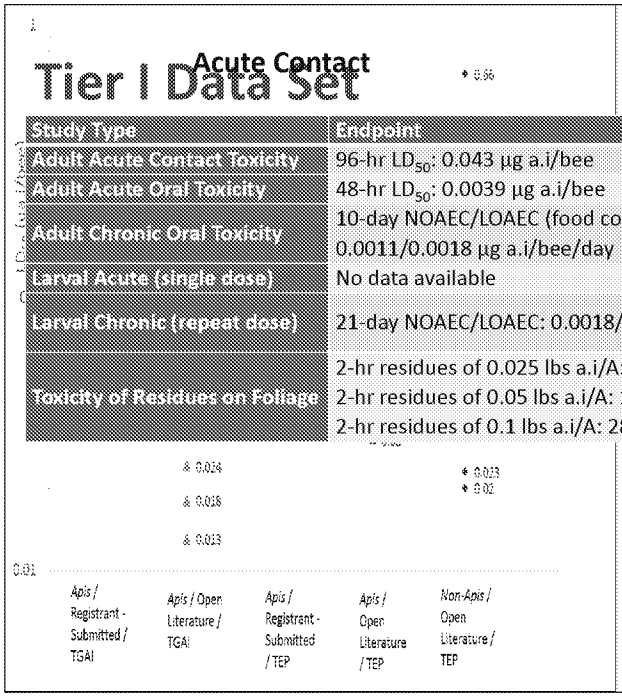
- Methods of application:
  - Foliar
  - Soil
  - Seed treatment
- Registered uses on variety of crops (including but not limited to):
  - Vegetables (tomatoes, legumes, broccoli, lettuce)
  - Fruits (apples, citrus, berries)
  - Cereal grains (corn, wheat, sorghum)
  - Tree nuts (walnuts, pecans)
  - Other (cotton, tobacco)
  - Non-agricultural (turf, ornamentals)

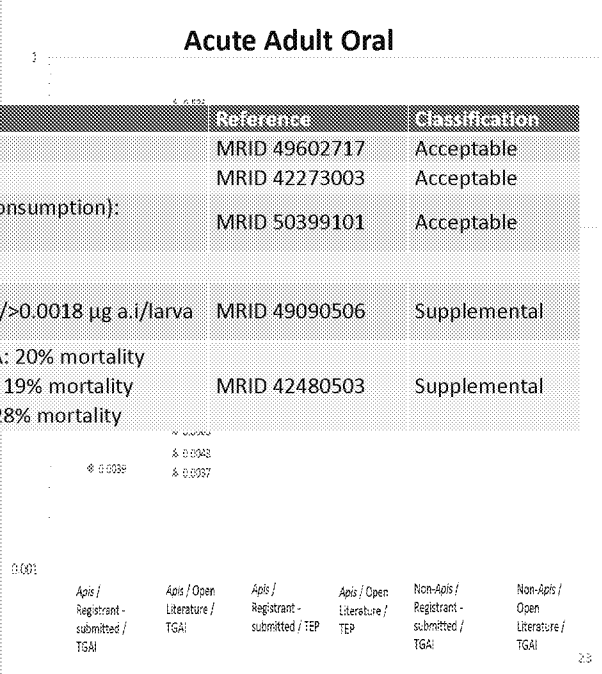
EPA

22

Tier I Data Set

Study Type	Endpoint	Reference	Classification
Adult Acute Contact Toxicity	96-hr LD_{50}: 0.043 µg a.i/bee	MRID 49602717	Acceptable
Adult Acute Oral Toxicity	48-hr LD_{50}: 0.0039 µg a.i/bee	MRID 42273003	Acceptable
Adult Chronic Oral Toxicity	10-day NOAEC/LOAEC (food consumption): 0.0011/0.0018 µg a.i/bee/day	MRID 50399101	Acceptable
Larval Acute (single dose)	No data available		
Larval Chronic (repeat dose)	21-day NOAEC/LOAEC: 0.0018/>0.0018 µg a.i/larva	MRID 49090506	Supplemental
Toxicity of Residues on Foliage	2-hr residues of 0.025 lbs a.i/A: 20% mortality 2-hr residues of 0.05 lbs a.i/A: 19% mortality 2-hr residues of 0.1 lbs a.i/A: 28% mortality	MRID 42480503	Supplemental





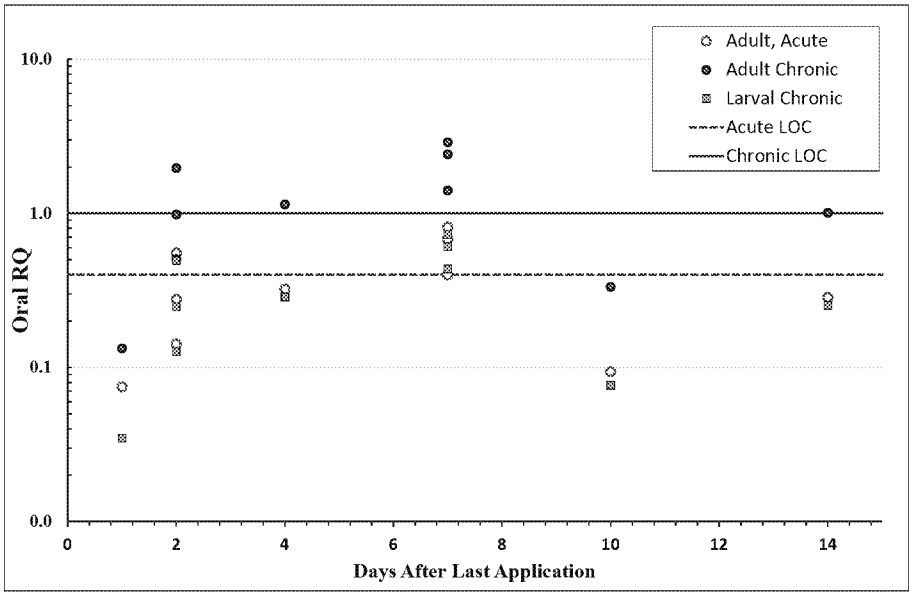
Tier I Default/Refined Assessment

Use pattern	Max. Single Appl. Rate (lbs a.i./A)	Bee Life Stage	Imidacloprid Oral Dose (µg a.i./bee)[1]	Acute RQ[2]	Chronic RQ[3]
Cucurbit vegetables	0.38	Adult	0.0173	3.0	11
		Larval	0.0079	N/A	2.8

Life stage	Caste or task in hive	Average age (in days)	Consumption Rates[4] Nectar (mg/day)	Pollen (mg/day)	Acute dose (µg a.i./bee)	Acute RQ[2]	Chronic dose (µg a.i./bee)[5]	Chronic RQ[3]
Larval	Worker	4	60	1.8	N/A		0.0007	0.40
		5	120	3.6			0.0015	0.81
	Drone	6+	130	3.6			0.0016	0.87
Adult	Worker (cell cleaning and capping)	0-10	60	6.65	0.0010	0.26	0.0009	0.84
	Worker (brood and queen tending, nurse bees)	6 to 17	140	9.6	0.0020	0.52	0.0019	1.8
	Worker (comb building, cleaning and food handling)	11 to 18	60	1.7	0.0007	0.19	0.0007	0.66
	Worker (foraging for pollen)	>18	43.5	0.041	0.0005	0.12	0.0005	0.43
	Worker (foraging for nectar)	>18	292	0.041	0.0032	0.82	0.0032	2.9
	Worker (maintenance of hive in winter)	0-90	29	2	0.0004	0.11	0.0004	0.36
	Drone	>10	335	0.0002	0.0026	0.66	0.0026	2.3

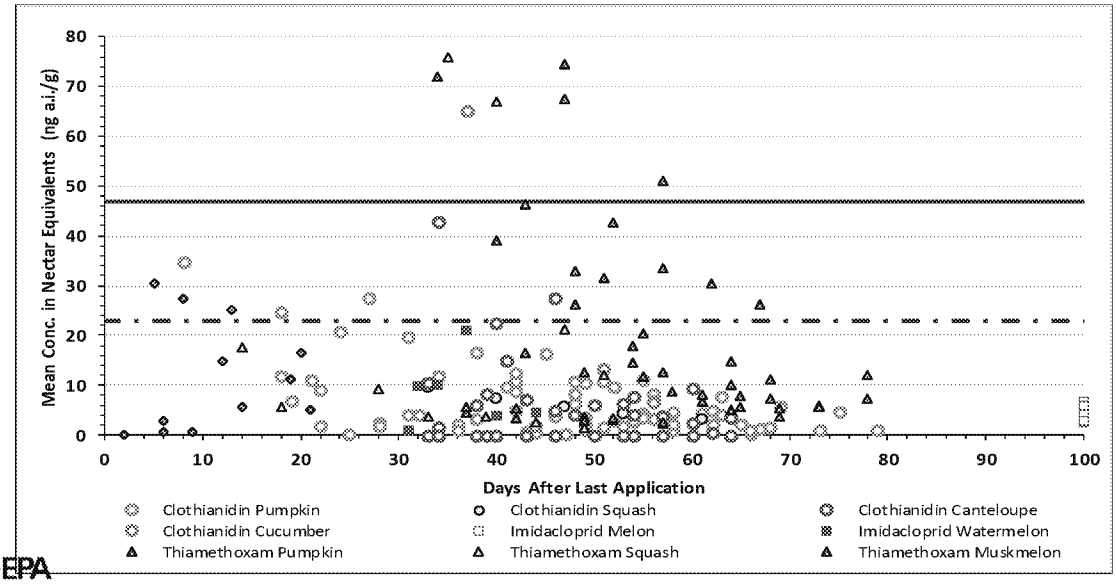
EPA

Refined Tier I Assessment



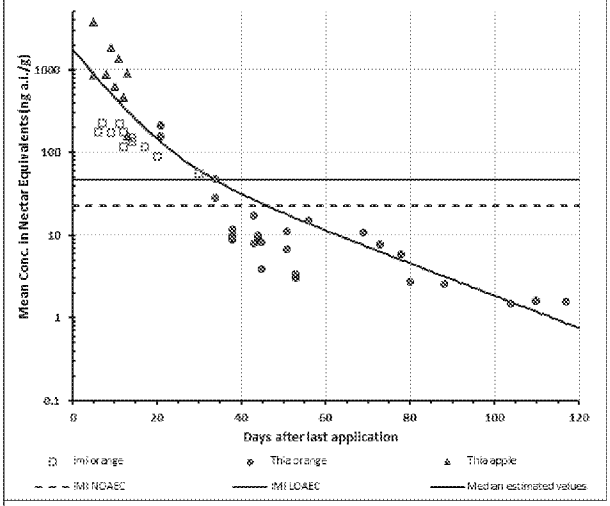
EPA

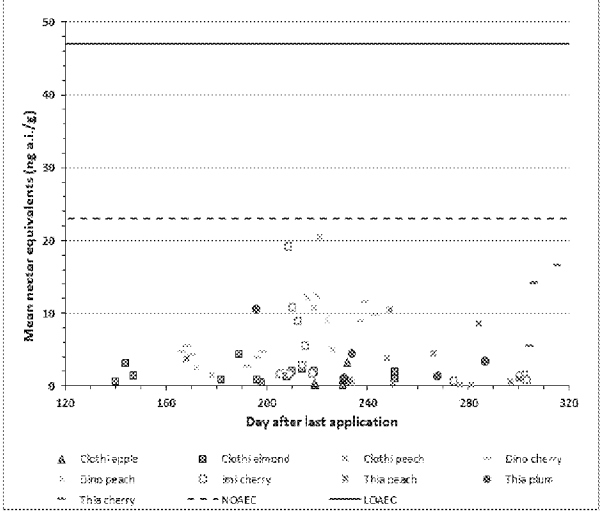
Tier II Assessment – Bridged Data



EPA

Tier II Assessment – Pre vs Post Bloom Application





EPA

Pre Bloom

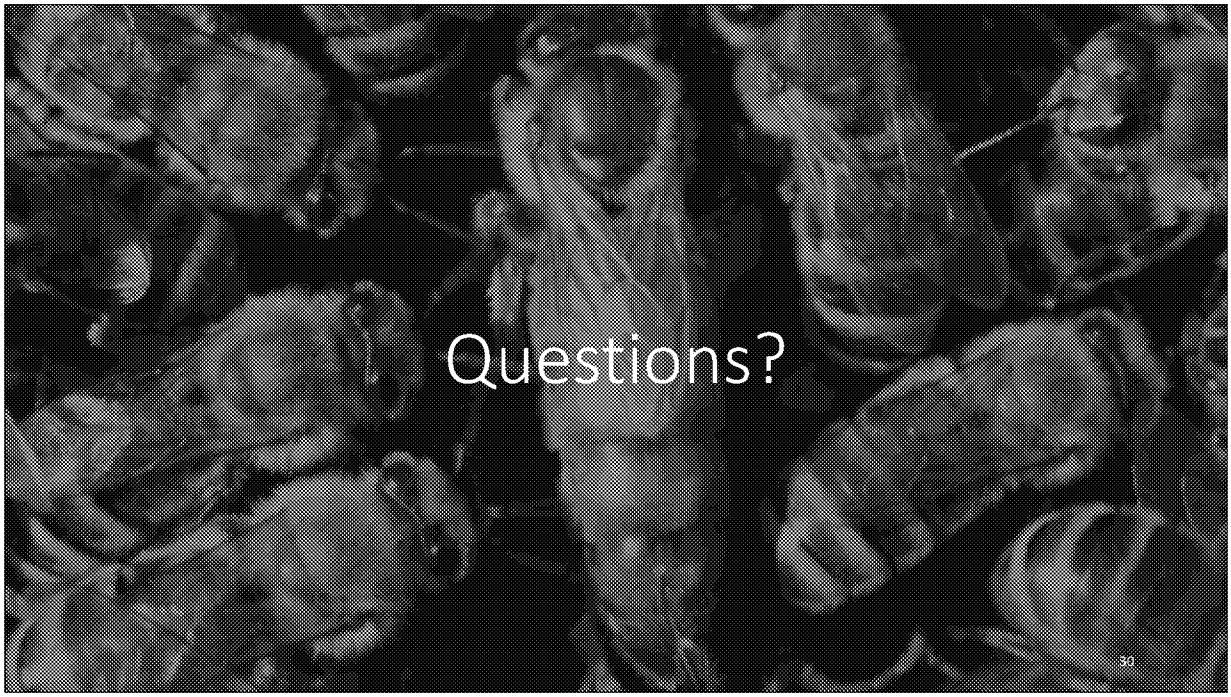
Post Bloom

Additional Lines of Evidence/Characterization

- Higher Tier exposure based on chemical specific or bridged?
- Frequency, magnitude, and duration of exceedances
- Attractiveness and bloom duration
- Managed pollinators required?
- Full field data available?
- Reported incidents available?
- Spatial extent of the risk?
- Other considerations (from higher tiered studies)

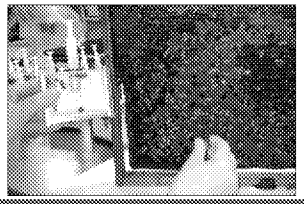
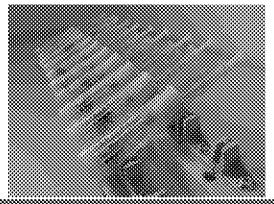
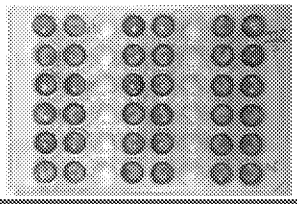
Future Work

- Bee-REX Updates
  - New default seed treatment value
  - Non-Apis Tier I estimates
  - Refined Tier I enhancements
- Population Modelling
- Higher Tier Guideline Standardization (ICPPR)
- Residue Bridging Expansion (PRTF)


Questions?
30

Appendix Slides

Weighing Data From Different Assessment Tiers

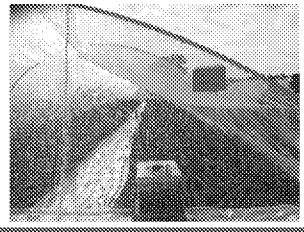




Tier 1 Effects Studies

Strengths	Limitations
• Controlled & documented exposure • High confidence in causality (dose-response) • Standard methods, repeatability • Statistical power generally good	• Exposure may lack environmental realism • Uncertainty in relating effects on individuals to colonies • Single stressor (usually)

EPA

Weighing Data From Different Assessment Tiers

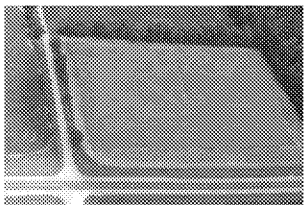




Tier 2 Semi-field (tunnel, feeding) studies w/ colonies

Strengths	Limitations
• Effects described at colony level • Partially controlled exposure • Generally high confidence in causality (dose-response) • *(Tunnel)*: contact + oral exposure, standardized test, 100% treated diet • *(Feeding):* long duration of exposure, greater replication, overwintering	• Lack of environmental realism (*e.g.,* confinement in tunnels, spiked sucrose feeding, surrogate crops) • Statistical power may be low • *(Tunnel):* Short duration, stress on bees • *(Feeding):* alternative foraging & exposure

EPA

Weighing Data From Different Assessment Tiers



Tier 3 Full Field Studies

Strengths	Limitations
• Effects described at colony level • Exposure reflects actual application practices to the crop(s) • Multiple stressors (environmental, pesticides) may be included	• Quantifying exposure of bees • Size of treated field vs. bees' foraging area • Results tend to be highly specific to crop, site(s) and landscape characteristics • Statistical power is often low

EPA